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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	**BEFORE THE BOARD OF PATENT**
	)	**APPEALS AND INTERFERENCES**
Boris P. Kovatchev et al.	)	
	)	Appeal No.:
Serial No. 10/524,094	)	
	)	Examiner: L. Clow
Filed: February 9, 2005	)	
	)	Group Art Unit: 1631
For: Method, system, and computer program product for the processing of self-monitoring blood glucose (SMBG) data to enhance diabetic self-management	)	
	)	January 13, 2010

BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

This is an appeal from the final rejection of claims 1 – 39 and 112 - 226 of the above-identified application, which claims were finally rejected in the Office action dated June 9, 2009. A Notice of Appeal was timely filed on October 9, 2009. A two-month extension of time from December 9, 2009 to February 9, 2010 for filing a brief in support of appeal is requested.

REAL PARTY IN INTEREST

The real party in interest in this case is University of Virginia Patent Foundation, of Charlottesville, Virginia.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

STATUS OF THE CLAIMS

Claims 1 – 226 are pending in the application and stand finally rejected. Claims 40 – 111 stand withdrawn from further consideration on the merits. Claims 1, 19, 37, 38, 135, 155, 175, 195, 215 and 221 constitute the independent claims on appeal. This appeal is directed to claims 1 – 39 and 112 – 226.

STATUS OF AMENDMENTS

The Advisory action dated October 15, 2009 indicated that the amendment after final rejection filed in this application on September 9, 2009 would be entered, and the Advisory action dated September 18, 2009 indicated that Appellant's response had overcome the rejection based on the first paragraph of 35 U.S.C. § 112.

SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention relates generally to the field of medical diagnostics, and in particular to a computer-based system and method for management of diabetes in individuals.

Specifically, the invention relates to glycemic control of individuals with diabetes, by determining glycosylated hemoglobin (HbA_{1c} and HbA_1) levels and predicting risk of incurring hypoglycemia, from collected self-monitored blood glucose data (SMBG). Severe hypoglycemia is a possible adverse effect of intensive insulin therapy. It is well-known that glycosylated hemoglobin is a marker for the glycemic control of individuals with either Type I or Type II diabetes. It is also known that HbA_{1c} reflects the average BG levels of a patient over the previous two months. Contemporary home blood glucose (BG) monitors allow the frequent measurement of blood glucose levels, but there are no reliable methods for evaluating HbA_{1c} and recognizing imminent risk of hypoglycemia based on SMBG readings. The present invention provides such a method, for evaluating HbA_{1c} and the risk of hypoglycemia from SMBG data collected from an individual, such as through use of a home BG monitor.

Claim 1

In accordance with the invention as set forth in claim 1, a method is provided for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:

pre-processing the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7);

estimating HbA_{1c} by applying at least one predetermined formula to said derived BG data (page 12, lines 17 – 21; page 76, lines 9 - 35):

validating the estimate via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29);

electronically transforming the estimate into a visual depiction (page 19, lines 12 – 15; page 89, line 5 to page 91, line 5); and

outputting the visual depiction of the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 19

In accordance with the invention as set forth in claim 19, a system is provided for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data (page 22, line 27); and

a processor programmed to (page 22 , lines 16 – 19):

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7),

estimate HbA_{1c} by applying at least one predetermined formula to said derived BG data (page 12, lines 17 – 21; page 76, lines 9 - 35),

validate the estimate via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29); and

output the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 37

In accordance with the invention as set forth in claim 37, a system is provided for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient (page 20, lines 17 – 28);

a database component operative to maintain a database identifying said BG data (page 22, line 27); and

a processor programmed to (page 22 , lines 16 – 19):

pre-process the acquired BG data to convert the acquired BG data into derived BG data derived from said acquired BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7);

estimate HbA_{1c} by applying at least one predetermined formula to said derived BG data (page 12, lines 17 – 21; page 76, lines 9 - 35);

validate the estimate via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29); and

output the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 38

In accordance with the invention as set forth in claim 38, a computer program product is provided comprising a tangible computer readable medium having computer program logic for enabling at least one processor in a computer system to evaluate the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration (Fig. 6, memory 608, 610, 618, 622), said computer program logic comprising:

pre-processing of the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7),

estimating HbA_{1c} by applying at least one predetermined formula to said derived BG data (page 12, lines 17 – 21; page 76, lines 9 - 35), and

validation of the estimate via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29); and

outputting the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 135

In accordance with the invention as set forth in claim 135, a method is provided for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:

pre-processing the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7),

validation of a sample of the collected BG data via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29),

estimating HbA_{1c} from said derived BG data if the sample is valid (page 12, lines 17 – 21; page 76, lines 9 - 35),

electronically transforming the estimate into a visual depiction (page 19, lines 12 – 15; page 89, line 5 to page 91, line 5), and

outputting the visual depiction of the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 155

In accordance with the invention as set forth in claim 155, a system is provided for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data (page 22, line 27); and

a processor programmed to (page 22 , lines 16 – 19):

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7),

validate a sample of the collected BG data via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29), and

estimate HbA_{1c} from said derived BG data if the sample is valid (page 12, lines 17 – 21; page 76, lines 9 - 35); and

output the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 175

In accordance with the invention as set forth in claim 175, a system is provided for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient (page 20, lines 17 – 28);

a database component operative to maintain a database identifying said BG data (page 22, line 27); and

a processor programmed to (page 22 , lines 16 – 19):

pre-process the acquired BG data to convert the acquired BG data into derived BG data derived from said acquired BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7);

validate a sample of the acquired BG data via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29);

estimate HbA_{1c} from said derived BG data if the sample is valid (page 12, lines 17 – 21; page 76, lines 9 - 35); and

output the HbA_{1c} estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 195

In accordance with the invention as set forth in claim 195, a method is provided for evaluating the HbA_{1c} of a patient without the need for prior HbA1c information based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:

pre-processing the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7),

validation of a sample of the collected BG data via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29),

estimating HbA_{1c} from said derived BG data if the sample is valid (page 12, lines 17 – 21; page 76, lines 9 - 35);

electronically transforming the estimate into a visual depiction (page 19, lines 12 – 15; page 89, line 5 to page 91, line 5); and

outputting the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 215

In accordance with the invention as set forth in claim 215, a system is provided for evaluating the HbA_{1c} of a patient without the need for prior HbA_{1c} information based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data (page 22, line 27); and

a processor programmed to (page 22 , lines 16 – 19):

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7),

validate a sample of the collected BG data via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29), and

estimate HbA_{1c} from said derived BG data if the sample is valid (page 12, lines 17 – 21; page 76, lines 9 - 35); and

output the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 221

In accordance with the invention as set forth in claim 221, a system for evaluating the HbA_{1c} of a patient without the need for prior HbA_{1c} information based on

blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient (page 20, lines 17 – 28);

a database component operative to maintain a database identifying said BG data (page 22, line 27); and

a processor programmed to (page 22 , lines 16 – 19):

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7);

validate a sample of the collected BG data via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29);

estimate HbA_{1c} from said derived BG data if the sample is valid (page 12, lines 17 – 21; page 76, lines 9 - 35); and

output the HbA_{1c} estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

This appeal presents the following issues for review by the Board:

1) Whether the Examiner erred in rejecting claims 1 – 18, 135 – 154, and 195 – 214 as allegedly being directed to non-statutory subject matter;

2) Whether the Examiner erred in rejecting claims 1 – 39 and 112 – 226 as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

ARGUMENT

The Rejection of Claims 1 – 18, 135 – 154, and 195 - 214 Is Improper

Claims 1 – 18, 135 – 154, and 195 – 214 have been deemed non-statutory "because they also read on abstract ideas." Final Rejection at 3 (emphasis added). This conclusion is erroneous.

Initially, the use of the term "also" in the final rejection indicates or at least implies recognition that the claims "read on" non-abstract ideas, or in other words practical applications of useful technology in the physical realm, which the patent laws are intended to protect. In fact, the claimed invention is not directed to "an abstract idea."

For example, claims 1, 135 and 195 are directed to a method for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on collected blood glucose (BG) data. There is nothing "abstract" about glycosylated hemoglobin, blood glucose levels, or a patient from which blood glucose data is collected. All are physical phenomena. Thus, the conclusion in the first instance that the claims are directed to "an abstract idea" is incorrect. The claims are directed to a specific evaluation of the composition of a diabetic patient's blood for assessment of a potential hypoglycemic condition, and

communicating the evaluation to a user, so that proper medical treatment may be administered to the patient.

The claims are not directed to abstract intellectual concepts such as converting binary-coded-decimal numbers to binary numbers, as in Gottschalk v. Benson, 409 U.S. 63,175 USPQ 673 (1972). Neither are the claims directed to mental processes, such as managing the consumption risk costs of a commodity, as in In re Bilski, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008). Neither are the claims directed to phenomena of nature, such as the properties of inhibition or of non-inhibition in Rhizobia bacteria, as in Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

To the contrary, the appealed claims to a specific method of estimating the glycosylated hemoglobin of a patient and communicating the estimate to a user, are directed to a method that pertains to analysis of quantitative physical characteristics of a physical patient, and that has practical application in the prevention or treatment of an adverse physical condition of a patient. Because the claimed method is applied to data representative of the physical element of a patient's blood composition, it meets the "transformation" test because it converts SMBG data representative of blood glucose, to an estimate of HbA_{1c} data representative of glycosylated hemoglobin.

Further, the claims meet the test for "transformation" enunciated in Bilski. In Bilski, the Court explained that the "transformation" part of the test is met where the data represents physical and tangible objects, and electronic transformation of data into a visual depiction is set forth:

> In contrast, we held one of Abele's dependent claims to be drawn to patent-eligible subject matter where it specified that "said data is X-ray attenuation data produced in a two dimensional field by a computed tomography scanner." Abele, 684 F.2d at 908-09. This data clearly represented physical and tangible objects, namely the structure of bones, organs, and other body tissues. Thus, the transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly-claimed process patent-eligible.
>
> We further note for clarity that the electronic transformation of the data itself into a visual depiction in Abele was sufficient; the claim was not required to involve any transformation of the underlying physical object that the data represented. We believe this is faithful to the concern the Supreme Court articulated as the basis for the machine-or-transformation test, namely the prevention of pre-emption of fundamental principles. So long as the claimed process is limited to a practical application of a fundamental principle to transform specific data, and the claim is limited to a visual depiction that represents specific physical objects or substances, there is no danger that the scope of the claim would wholly pre-empt all uses of the principle.

88 USPQ2d at 1397.

Here, the claims all set forth electronic transformation of the estimate data into a visual depiction that is presented to a user, and thus, satisfies the "transformation" test.

The final rejection purports, but fails, to rebut this fact. Instead, the final rejection alleges that "the 'transformation' by electronically transforming an estimate, is not central to the purpose of the claimed subject matter." This assertion, however, is

directly at odds with the Court's statement in Bilski, that "[s]o long as the claimed process is limited to a practical application of a fundamental principle to transform specific data, and the claim is limited to a visual depiction that represents specific physical objects or substances, there is no danger that the scope of the claim would wholly pre-empt all uses of the principle." 88 F.3d at 1397.

Moreover, the communication of the HbA_{1c} evaluation result to a user indeed can be considered "central" to the invention, to the extent that the evaluation must be perceived by an entity external to the determination of the estimate itself, so that appropriate diagnosis and/or treatment may be prescribed and administered to the patient.

The Advisory action of October 15, 2009 further alleges that "[c]laim limitations directed to obtaining or outputting data using an apparatus or machine are considered insignificant pre-solution and post-solution activity." Again, this position is irreconcilable with the Court's guidance in Bilski, as discussed above. The case law regarding "insignificant post-solution activity" is applicable only to mathematical manipulation of abstract data, and not to data representative of "specific physical objects or substances" as is the case here.

This position additionally is at odds with the statement in the same Advisory action that a practical application of an abstract idea "can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. § 101." Here, on the one hand, the Examiner

states that the claimed invention, allegedly directed to an abstract idea, may have practical application if tied to another statutory class of invention, but on the other hand, the Examiner dismisses the tying to such other statutory class as insufficient because it is "insignificant post-solution activity." Such contradictory positions illustrate that a proper analysis of the claimed subject matter under applicable legal precedent has not be undertaken. If "post-solution activity" is insignificant, then by definition there cannot be any "practical application" of a concept or idea.

In view of the foregoing, the rejection of claims as being directed to non-statutory subject matter is in error, and must be reversed.

The Rejection of Claims 1 – 39 and 112 – 226 as Being Indefinite Is Improper

The rejection of claims 1 – 39 and 112 – 226 under the second paragraph of 35 U.S.C. § 112 as being indefinite, is improper and should be reversed. The final rejection alleges that the language "pre-processing the collected BG data to convert the collected BG data into derived BG data derived from collected BG data" is unclear as to what is being derived about the BG data.

MPEP § 2173.02, explains, "[d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made."

In particular, the specification explains that the pre-processing of the data comprises a number of actions, including conversion of plasma to whole blood BG mg/dl; conversion of BG in mg/dl to units of mmol/l; and computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1). Specification page 11, lines 20 – 27. This derived data, which is derived from the collected BG data, is then used to develop the HbA_{1c} estimate. See Specification at page 12, lines 17 – 20; page 31, line 3 to page 32, line 4.

Here, the question "what is being derived about the BG data" arises only when the claim is considered in a vacuum, which is not a proper analysis. The question is answered completely simply by making reference to the specification, which according to fundamental principles of claim construction must be done prior to analyzing the claim for compliance with 35 U.S.C. § 112. Consequently, the claims are not indefinite but instead fully comply with the requirements of 35 U.S.C. § 112. Reversal of this ground of rejection is indicated and is respectfully requested.

CONCLUSION

In view of the foregoing, claims 1 – 39 and 112 – 226 are submitted to be directed to a new and unobvious method, system and computer program product for evaluation of the glycosylated hemoglobin of a patient, which is not taught by the prior art and which fully comply with the statutory category of invention and definiteness requirements of the patent laws. The Honorable Board is respectfully requested to reverse all grounds of rejection and to direct the passage of this application to issue.

Please charge any fee or credit any overpayment pursuant to 37 CFR 1.16 or 1.17 to Novak Druce Deposit Account No. 14-1437.

Respectfully submitted,

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APPENDIX OF CLAIMS ON APPEAL

1. (previously presented) A method for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:

   pre-processing the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

   estimating HbA_{1c} by applying at least one predetermined formula to said derived BG data,

   validating the estimate via sample selection criteria;

   electronically transforming the estimate into a visual depiction; and

   outputting the visual depiction of the estimate to a user.

2. (original) The method of claim 1, wherein said first predetermined duration is about 60 days.

3. (original) The method of claim 1, wherein said first predetermined duration ranges from about 45 days to about 75 days.

4. (original) The method of claim 1, wherein said first predetermined duration ranges from about 45 days to about 90 days.

5. (previously presented) The method of claim 1, wherein the pre-processing of the data comprises:

   conversion of plasma data to whole blood BG mg/dl;

   conversion of BG measured in mg/dl to units of mmol/l; and

   computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

6. (previously presented) The method of claim 1, wherein the preprocessing of the data comprises :

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals ,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

7. (original) The method of claim 6, wherein the N06, N12, N24 are percentage of

SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

8. (original) The method of claim 6, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

9. (original) The method of claim 8, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

10. (original) The method of claim 9, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

11. (previously presented) The method of claim 10 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration,

said estimating HbA_{1c} comprising:

a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 6.

RLO1 is the Low BG Index of claim 6.

RHI1 is the High BG Index of claim 6; or

c) HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA1c reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 6; or

d) HbA_{1c} = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 6.

12. (original) The method of claim 11, wherein said second predetermined duration is about three months.

13. (original) The method of claim 11, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

14. (original) The method of claim 11, wherein said second predetermined duration ranges from about 2.5 months to six months.

15. (previously presented) The method of claim 11, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 6

RHI1 is the High BG Index of claim 6; or

d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%).

wherein

N06 is the percentage of readings during the night of claim 6.

16. (original) The method of claim 15, wherein said third predetermined duration is at least 35 days.

17. (original) The method of claim 15, wherein said third predetermined duration ranges from about 35 days to about 40 days.

18. (original) The method of claim 15, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

19. (currently amended) A system for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

estimate HbA_{1c} by applying at least one predetermined formula to said derived BG data,

validate the estimate via sample selection criteria; and

output the estimate to a user.

20. (original) The system of claim 19, wherein said first predetermined duration is about 60 days.

21. (original) The system of claim 19, wherein said first predetermined duration ranges from about 45 days to about 75 days.

22. (original) The system of claim 19, wherein said first predetermined duration ranges from about 45 days to about 90 days.

23. (previously presented) The system of claim 19, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

24. (previously presented) The system of claim 19, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l) via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

25. (original) The system of claim 24, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

26. (original) The system of claim 24, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

27. (original) The system of claim 26, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

28. (original) The system of claim 27, comprising providing further correction of the

estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is ≤about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

29. (previously presented) The system of claim 28 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, wherein said estimating HbA_{1c} comprises :

a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 24,

RLO1 is the Low BG Index of claim 24,

RHI1 is the High BG Index of claim 24; or

c) HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 24; or

d) HbA_{1c} = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 24.

30. (original) The system of claim 29, wherein said second predetermined duration is about three months.

31. (original) The system of claim 29, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

32. (original) The system of claim 29, wherein said second predetermined duration ranges from about 2.5 months to six months.

33. (previously presented) The system of claim 29, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 24,

RHI1 is the High BG Index of claim 24; or

d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 24.

34. (original) The system of claim 33, wherein said third predetermined duration is at least 35 days.

35. (original) The system of claim 33, wherein said third predetermined duration ranges from about 35 days to about 40 days.

36. (original) The system of claim 33, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

37. (previously presented) A system for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

pre-process the acquired BG data to convert the acquired BG data into derived BG data derived from said acquired BG data;

estimate HbA_{1c} by applying at least one predetermined formula to said derived BG data;

validate the estimate via sample selection criteria; and

output the estimate to a user.

38. (previously presented) A computer program product comprising a tangible computer readable medium having computer program logic for enabling at least one processor in a computer system to evaluate the HbA_{1c} of a patient based on

blood glucose (BG) data collected over a first predetermined duration, said computer program logic comprising:

pre-processing of the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

estimating HbA_{1c} by applying at least one predetermined formula to said derived BG data, and

validation of the estimate via sample selection criteria; and

outputting the estimate to a user.

39. (original) The computer program product of claim 38, wherein said computer program logic further comprises the steps of claim 11.

112. (previously presented) The method of claim 11, wherein the validation of the HbA1c estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 6

RHI1 is the High BG Index of claim 6; or

c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 6.

113. (original) The method of claim 112, wherein said third predetermined duration is at least about 35 days.

114. (previously presented) The system of claim 29, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 24

RHI1 is the High BG Index of claim 24; or

c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 24.

115. (original) The system of claim 114, wherein said third predetermined duration is at least about 35 days.

116. (previously presented) The system of claim 37, wherein said first predetermined duration is about 60 days.

117. (previously presented) The system of claim 37, wherein said first predetermined duration ranges from about 45 days to about 75 days.

118. (previously presented) The system of claim 37, wherein said first predetermined duration ranges from about 45 days to about 90 days.

119. (previously presented) The system of claim 37, wherein the pre-processing of the data comprises:

conversion of plasma data to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

120. (previously presented) The system of claim 37, wherein the preprocessing of the data comprises:

conversion of plasma data to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l) via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

121. (previously presented) The system of claim 120, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

122. (previously presented) The system of claim 120, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

123. (previously presented) The system of claim 122, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

124. (previously presented) The system of claim 123, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is ≤about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

125. (previously presented) The system of claim 124 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said system comprising:

said estimating HbA_{1c} using said at least one of four predetermined mathematical formulas defined as:

a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 120,

RLO1 is the Low BG Index of claim 120,

RHI1 is the High BG Index of claim 120; or

c) HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 120; or

d) HbA_{1c} = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 120.

126. (previously presented) The system of claim 125, wherein said second predetermined duration is about three months.

127. (previously presented) The system of claim 125, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

128. (previously presented) The system of claim 125, wherein said second predetermined duration ranges from about 2.5 months to six months.

129. (previously presented) The system of claim 125, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 120,

RHI1 is the High BG Index of claim 120; or

d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 120.

130. (previously presented) The system of claim 129, wherein said third predetermined duration is at least 35 days.

131. (previously presented) The system of claim 129, wherein said third predetermined duration ranges from about 35 days to about 40 days.

132. (previously presented) The system of claim 129, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

133. (previously presented) The system of claim 125, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 120

RHI1 is the High BG Index of claim 120; or

c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 120.

134. (previously presented) The system of claim 133, wherein said third predetermined duration is at least about 35 days.

135. (previously presented) A method for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:

pre-processing the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

validation of a sample of the collected BG data via sample selection criteria,

estimating HbA_{1c} from said derived BG data if the sample is valid,

electronically transforming the estimate into a visual depiction, and

outputting the visual depiction of the estimate to a user.

136. (previously presented) The method of claim 135, wherein said first predetermined duration is about 60 days.

137. (previously presented) The method of claim 135, wherein said first predetermined duration ranges from about 45 days to about 75 days.

138. (previously presented) The method of claim 135, wherein said first predetermined duration ranges from about 45 days to about 90 days.

139. (previously presented) The method of claim 135, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

140. (previously presented) The method of claim 135, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

$Scale=[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

141. (previously presented) The method of claim 140, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

142. (previously presented) The method of claim 140, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

143. (previously presented) The method of claim 142, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

144. (previously presented) The method of claim 143, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is ≤about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

145. (previously presented) The method of claim 144 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said method comprising:

estimating HbA_{1c} using at least one of four predetermined mathematical formulas defined as:

a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 140.

RLO1 is the Low BG Index of claim 140.

RHI1 is the High BG Index of claim 140; or

c) HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second

predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 140; or

d) HbA_{1c} = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 140.

146. (previously presented) The method of claim 145, wherein said second predetermined duration is about three months.

147. (previously presented) The method of claim 145, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

148. (previously presented) The method of claim 145, wherein said second predetermined duration ranges from about 2.5 months to six months.

149. (previously presented) The method of claim 145, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 140

RHI1 is the High BG Index of claim 140; or

d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%).

wherein

N06 is the percentage of readings during the night of claim 140.

150. (previously presented) The method of claim 149, wherein said third predetermined duration is at least 35 days.

151. (previously presented) The method of claim 149, wherein said third predetermined duration ranges from about 35 days to about 40 days.

152. (previously presented) The method of claim 149, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

153. (previously presented) The method of claim 145, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 149

RHI1 is the High BG Index of claim 140; or

c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 140.

154. (previously presented) The method of claim 153, wherein said third predetermined duration is at least about 35 days.

155. (previously presented) A system for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

validate a sample of the collected BG data via sample selection criteria, and

estimate HbA_{1c} from said derived BG data if the sample is valid; and

output the estimate to a user.

156. (previously presented) The system of claim 155, wherein said first predetermined duration is about 60 days.

157. (previously presented) The system of claim 155, wherein said first predetermined duration ranges from about 45 days to about 75 days.

158. (previously presented) The system of claim 155, wherein said first predetermined duration ranges from about 45 days to about 90 days.

159. (previously presented) The system of claim 155, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

160. (previously presented) The system of claim 155, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

161. (previously presented) The system of claim 160, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

162. (previously presented) The system of claim 160, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

163. (previously presented) The system of claim 162, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

164. (previously presented) The system of claim 163, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is ≤about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

165. (previously presented) The system of claim 164 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said system comprising:

estimating HbA_{1c} using at least one of four predetermined mathematical formulas defined as:

a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 160,

RLO1 is the Low BG Index of claim 160,

RHI1 is the High BG Index of claim 160; or

c) HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 160; or

d) HbA_{1c} = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 160.

166. (previously presented) The system of claim 165, wherein said second predetermined duration is about three months.

167. (previously presented) The system of claim 165, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

168. (previously presented) The system of claim 165, wherein said second predetermined duration ranges from about 2.5 months to six months.

169. (previously presented) The system of claim 165, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 160,

RHI1 is the High BG Index of claim 160; or

d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 160.

170. (previously presented) The system of claim 169, wherein said third predetermined duration is at least 35 days.

171. (previously presented) The system of claim 169, wherein said third predetermined duration ranges from about 35 days to about 40 days.

172. (previously presented) The system of claim 169, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

173. (previously presented) The system of claim 165, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 160

RHI1 is the High BG Index of claim 160; or

c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 160.

174. (previously presented) The system of claim 173, wherein said third predetermined duration is at least about 35 days.

175. (previously presented) A system for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

pre-process the acquired BG data to convert the acquired BG data into derived BG data derived from said acquired BG data;

validate a sample of the acquired BG data via sample selection criteria;

estimate HbA_{1c} from said derived BG data if the sample is valid; and

output the HbA_{1c} estimate to a user.

176. (previously presented) The system of claim 175, wherein said first predetermined duration is about 60 days.

177. (previously presented) The system of claim 175, wherein said first predetermined duration ranges from about 45 days to about 75 days.

178. (previously presented) The system of claim 175, wherein said first predetermined duration ranges from about 45 days to about 90 days.

179. (previously presented) The system of claim 175, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

180. (previously presented) The system of claim 175, wherein the pre-processing of the data comprises:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l) via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

181. (previously presented) The system of claim 180, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

182. (previously presented) The system of claim 180, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

183. (previously presented) The system of claim 182, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

184. (previously presented) The system of claim 183, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is ≤about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

185. (previously presented) The system of claim 184 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said system comprising:

estimating HbA_{1c} using at least one of four predetermined mathematical formulas defined as:

a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 180,

RLO1 is the Low BG Index of claim 180,

RHI1 is the High BG Index of claim 180; or

c) HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second

predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 180; or

d) HbA_{1c} = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 180.

186. (previously presented) The system of claim 185, wherein said second predetermined duration is about three months.

187. (previously presented) The system of claim 185, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

188. (previously presented) The system of claim 185, wherein said second predetermined duration ranges from about 2.5 months to six months.

189. (previously presented) The system of claim 185, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 180,

RHI1 is the High BG Index of claim 180; or

d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 180.

190. (previously presented) The system of claim 189, wherein said third predetermined duration is at least 35 days.

191. (previously presented) The system of claim 189, wherein said third predetermined duration ranges from about 35 days to about 40 days.

192. (previously presented) The system of claim 189, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

193. (previously presented) The system of claim 185, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 180

RHI1 is the High BG Index of claim 180; or

c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 180.

194. (previously presented) The system of claim 193, wherein said third predetermined duration is at least about 35 days.

195. (previously presented) A method for evaluating the HbA_{1c} of a patient without the need for prior HbA_{1c} information based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:

pre-processing the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

validation of a sample of the collected BG data via sample selection criteria,

estimating HbA_{1c} from said derived BG data if the sample is valid;

electronically transforming the estimate into a visual depiction; and

outputting the estimate to a user.

196. (previously presented) The method of claim 195, wherein said first predetermined duration is about 60 days.

197. (previously presented) The method of claim 195, wherein said first predetermined duration ranges from about 45 days to about 75 days.

198. (previously presented) The method of claim 195, wherein said first predetermined duration ranges from about 45 days to about 90 days.

199. (previously presented) The method of claim 195, wherein the preprocessing of

the data comprises:

conversion of plasma data to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

200. (previously presented) The method of claim 195, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l) via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

201. (previously presented) The method of claim 200, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

202. (previously presented) The method of claim 200, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

203. (previously presented) The method of claim 202, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

204. (previously presented) The method of claim 203, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is ≤about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

205. (previously presented) The method of claim 204 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said method comprising:

estimating HbA_{1c} using at least one of four predetermined mathematical formulas defined as:

a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 200,

RLO1 is the Low BG Index of claim 200,

RHI1 is the High BG Index of claim 200; or

c) HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 200; or

d) HbA_{1c} = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 200.

206. (previously presented) The method of claim 205, wherein said second predetermined duration is about three months.

207. (previously presented) The method of claim 205, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

208. (previously presented) The method of claim 205, wherein said second predetermined duration ranges from about 2.5 months to six months.

209. (previously presented) The method of claim 205, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 200

RHI1 is the High BG Index of claim 200; or

d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%).

wherein

N06 is the percentage of readings during the night of claim 200.

210. (previously presented) The method of claim 209, wherein said third predetermined duration is at least 35 days.

211. (previously presented) The method of claim 209, wherein said third predetermined duration ranges from about 35 days to about 40 days.

212. (previously presented) The method of claim 209, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

213. (previously presented) The method of claim 205, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 149

RHI1 is the High BG Index of claim 200; or

c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 200.

214. (previously presented) The method of claim 213, wherein said third predetermined duration is at least about 35 days.

215. (previously presented) A system for evaluating the HbA_{1c} of a patient without the need for prior HbA_{1c} information based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

validate a sample of the collected BG data via sample selection criteria, and

estimate HbA_{1c} from said derived BG data if the sample is valid; and

output the estimate to a user.

216. (previously presented) The system of claim 215, wherein said first predetermined duration is about 60 days.

217. (previously presented) The system of claim 215, wherein said first predetermined duration ranges from about 45 days to about 75 days.

218. (previously presented) The system of claim 215, wherein said first predetermined duration ranges from about 45 days to about 90 days.

219. (previously presented) The system of claim 215, wherein the preprocessing of the data comprises:

conversion of plasma data to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

220. (previously presented) The system of claim 215, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

$Scale=[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

221. (previously presented) A system for evaluating the HbA_{1c} of a patient without the need for prior HbA_{1c} information based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data;

validate a sample of the collected BG data via sample selection criteria;

estimate HbA_{1c} from said derived BG data if the sample is valid; and

output the HbA_{1c} estimate to a user.

222. (previously presented) The system of claim 221, wherein said first predetermined duration is about 60 days.

223. (previously presented) The system of claim 221, wherein said first predetermined duration ranges from about 45 days to about 75 days.

224. (previously presented) The system of claim 221, wherein said first predetermined duration ranges from about 45 days to about 90 days.

225. (previously presented) The system of claim 221, wherein the preprocessing of the data comprises:

conversion of plasma data to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

226. (previously presented) The system of claim 221, wherein the preprocessing of the data is defined as:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

$Scale=[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

EVIDENCE APPENDIX

None.

RELATED APPEALS APPENDIX

None.